

## REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on January 31, 2006. A petition for a one month extension of time is submitted herewith. The Director is authorized to charge \$120.00 for the petition for extension of time or any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112843-43 on the account statement.

Claims 1, 3-4, 6-10 and 12-20 are pending in this application. Claims 2, 5 and 11 were previously canceled. In the Office Action, Claims 1, 3-4, 6-10 and 12-20 are rejected under 35 U.S.C. §112, first paragraph, Claims 3-4, 6-9 and 12 are rejected under 35 U.S.C. §112, second paragraph, and Claims 1, 3-4, 6-10 and 12-20 are rejected under 35 U.S.C. §103. In response Claims 3-4 and 6-9 have been amended, and Claim 12 has been canceled. This amendment does not add new matter. In view of the amendment and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claims 1, 3-4, 6-10 and 12-20 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Patent Office alleges that the term "mixtures thereof" does not have support in the specification.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Applicants respectfully submit that the specification provides sufficient guidance to support the term "mixtures thereof" with respect to the present claims. For example, the specification teaches that a method of producing the claimed composition involves blending the whey protein and casein protein together with free arginine, free histidine and tryptophan rich milk protein and homogenizing the blended mixture. See, specification, page 2, lines 19-22. The specification also teaches that the claimed composition can be prepared in any suitable manner, for example, by blending a number of ingredients together with the protein components to produce the claimed composition. See, page 7, line 31 to page 29. As a result, one having ordinary skill in the art would understand that the

Applicants had possession of a "mixture thereof" of the protein components as recited, in part, by the present claims in view of the specification.

Applicants have canceled Claim 12. Based on at least these noted reasons, Applicants believe that Claims 1, 3-4, 6-10 and 12-20 fully comply with 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 1, 3-4, 6-10 and 12-20 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 3-4, 6-9 and 12 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended Claims 3-4 and 6-9 and canceled Claim 12 to address the informalities cited by the Patent Office. Based on at least these noted reasons, Applicants believe that Claims 3-4, 6-9 and 12 fully comply with 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 3-4, 6-9 and 12 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1, 3-4, 6-10 and 12-20 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. JP 002158762 ("*JP '762*") in view of U.S. Patent No. 6,757,158 to Erdmann et al. ("*Erdmann*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

The present invention is direct, in part, to a composition for an infant formula and a method for its preparation. For example, the composition comprises specific components, which provide a balanced amount of all essential amino acids to an infant. Such a composition specifically comprises hydrolysed sweet whey protein from which caseino-glyco-macropetide (CGMP) has been removed. This provides a composition with reduced threonine (e.g. reduced nitrogen load) and increased tryptophan content and can be a hypoallergenic infant formula. In contrast, Applicants respectfully submit that, even if combinable, all of the claimed elements are not taught or suggested by the cited references.

Regarding *JP '762*, Applicants respectfully submits that *JP '762* is directed to a preparation of a nutritive composition that may be used as an infant food and may specifically be suitable for the treatment of some disorders. It should also be noted that *JP '762* does not primarily pertain to an infant formula for healthy babies. The composition disclosed in *JP '762* is a pediatric formulation for sick babies suffering from for example from urea cycle and kidney

disorders. This explains the presence in the composition of a wide range of the free amino acids, the suggested proportions of lipid and carbohydrate that may be used (which are different from those usually found in infant formula) and the suggestion that honey can be added to disguise the bitter taste of the amino acids.

In view of the teachings of *JP '762*, one having ordinary skill in the art would understand that *JP '762* neither teaches nor suggests using hydrolyzed sweet whey protein as required, in part, by the present claims. The Patent Office admits same. See, Office Action, page 9. *JP '762* also fails to teach or suggest hydrolysed sweet whey protein from which CGMP has been removed. Finally, *JP '762* does not disclose a milk protein having 5% or more of amino acids as tryptophan as required, in part, by the present claims. Although *JP '762* mentions that the composition may be easily digested and utilized by the babies, *JP '762* does not disclose that the protein is hydrolysed in any preparation step. Moreover, by teaching addition free threonine *JP '762* teaches away from the present invention. Consequently, *JP '762* is deficient with respect to the presently claimed subject matter.

*Erdmann* is directed to a process for treatment of a lactic raw material. The process relates to the extraction of glycomacropeptide (GMP) from the raw material by subjecting the material in a solution having a pH of about 1 to 4.5 to an anionic resin to which GMP selectively binds. Nevertheless, *Erdmann* fails to disclose or suggest a hydrolysed sweet whey protein from which the CGMP been removed. *Erdmann* also fails to disclose or suggest the specific amino acid composition cited, in part, by the present claims.

Applicants also respectfully submit that the Patent Office's assertion that *Erdmann* teaches a hydrolysed sweet whey is improper. See, Office Action, page 9. For example, *Erdmann* does not use hydrolysed sweet whey as a starting material in the process by which the CGMP is removed. Accordingly, "the product of hydrolysis, by a protease of a native casein obtained by acid precipitation of skimmed milk" recited in *Erdmann* describes the process in which skimmed milk is treated to precipitate the casein leaving the whey protein in solution. In this process, CGMP is cleaved from kappa casein and remains in solution with the whey proteins. This is the same as the process described at page 24, lines 25-31 in the present specification. Neither the sweet whey starting material nor the modified sweet whey produced by removal of the CGMP are hydrolysed. Thus, contrary to what is stated by the Patent Office,

*Erdmann* fails to disclose or suggest the use of a hydrolysed sweet whey as a starting material for the process disclosed therein. Further, one having ordinary skill in the art would understand that a hydrolysed modified sweet whey could only be obtained by first removing the CGMP and then subjecting the modified sweet whey to hydrolysis and not the other way round.

For the reasons discussed above, even if combinable, *JP '762* and *Erdmann* do not teach, suggest, or even disclose all of the elements of the present claims, and thus, fail to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1, 3-4, 6-10 and 12-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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